

## **Radiological/Nuclear Medical Countermeasure Product Development Program**

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The official link for this solicitation is: <http://grants.nih.gov/grants/guide/pa-files/PA-09-093.html>

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Description:

### **Purpose**

The purpose of this funding opportunity is to solicit Small Business Innovation Research (SBIR) grant applications (Phase I [R43] and Phase II [R44, both new and renewal applications]) that are focused on specific Investigational New Drug/Investigational Device Exemption (IND/IDE) enabling product development activities for radiological/nuclear medical countermeasures leading to IND or IDE submission packages to the U.S. Food and Drug Administration (FDA). This FOA will support non-clinical and pre-clinical IND/IDE-enabling activities that include efficacy studies to optimize formulation, dose, and dose scheduling; statistically valid developmental efficacy studies; GLP-pilot efficacy studies to inform the design of GLP pivotal efficacy study protocols; and to conduct drug product stability studies, drug product current Good Manufacturing Practice (cGMP) manufacturing scale-up, Good Laboratory Practice (GLP) toxicology and pharmacology safety studies, pharmacokinetic and metabolism studies, development of GLP analytical methods for efficacy studies and product characterization, and completion of IND or IDE packages for FDA submission. These product development efforts will advance the new medical countermeasures towards Phase I clinical trial safety studies, GLP animal model pivotal efficacy studies, and FDA licensure.

GLP animal model pivotal efficacy studies are **NOT** supported by this FOA.

Phase I clinical safety trials are **NOT** supported by this FOA. Applicants interested in carrying out Phase I clinical trials must submit a separate application and are encouraged to consult the NIAID Clinical Trial Planning (R34) Grants program (<http://grants.nih.gov/grants/guide/pa-files/PA-05-112.html>).

## **Background and Research Objectives**

Very few medical products exist that have been shown to counter the acute and long-term injuries that can result from a nuclear or radiological accident or attack. The threat of attack has grown in recent years, with increased activity of global terrorist organizations and a rise in illicit trafficking of radioactive materials. In July 2004, the President signed Project BioShield into law ([http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108\\_cong\\_public\\_laws&docid=f:publ090.108.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ090.108.pdf)). This is a Federal effort to develop and make available drugs and vaccines to protect against terrorist-mediated chemical, biological, or radiological/nuclear exposure. Project BioShield has initiated several activities directed at the development, licensure and stockpiling of FDA-approved countermeasures for radiological and nuclear injury. The National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) was given the responsibility by the Department of Health and Human Services (DHHS) to identify, characterize and develop new medical countermeasure products against radiological and nuclear attacks that may cause a public health emergency.

In 2005, the NIH published a Strategic Plan and Research Agenda for Medical Countermeasures against Radiological and Nuclear Threats ([http://www3.niaid.nih.gov/about/overview/planningPriorities/RadNuc\\_StrategicPlan.pdf](http://www3.niaid.nih.gov/about/overview/planningPriorities/RadNuc_StrategicPlan.pdf)). This agenda includes focused product development, including medical countermeasures for mitigation and treatment of acute radiation syndromes (ARS), as well as development of radionuclide decorporation agents, and biodosimetry devices. Several NIAID-supported contract and grants programs (<http://www3.niaid.nih.gov/research/topics/radnuc/default.htm>) have been established to initiate research and product development efforts. The grant programs established eight Centers for Medical Countermeasure against Radiation (CMCRs) for research on mitigation and treatment of acute radiation syndromes (ARS), new programs to develop novel radionuclide decorporation agents, and programs to identify and evaluate biodosimetry techniques and devices. Other grant programs supporting the research and development of medical countermeasures against specific radiation injuries in tissues, such as hematopoietic, gastrointestinal, cutaneous, lung, and combined injuries, have been implemented. In addition, contract programs have identified and evaluated medical countermeasures for mitigation and treatment of ARS and have identified and evaluated new forms of diethylenetriaminepentaacetate (DTPA) with significantly increased oral bioavailability. Continued successful development of medical countermeasures, ARS mitigators or treatments, radionuclide decorporation agents, and biodosimetry techniques and devices will fill an important need for the Strategic National Stockpile (SNS).

The NIAID encourages the development of 1) effective therapeutic products to mitigate and/or treat short-term and long-term or delayed effects of radiation exposures, 2) radionuclide decorporation agents to eliminate internal contamination, and 3) biodosimetry devices and methods to measure external or internal radiation dose. The spectrum of research and development activities may include proof of principle studies, preclinical efficacy work, statistically valid developmental efficacy studies, GLP-pilot studies to inform the design of GLP pivotal efficacy study protocols, non-clinical determination of safety, toxicology and metabolism, formulation development as well as determination of dose and dose scheduling, cGMP manufacturing scale-up and drug product stability studies, development of GLP analytical methods for efficacy studies, product characterization, and completion of IND or IDE packages for FDA submission. These activities will support the development, preparation and submission of IND and IDE for eventual FDA licensure, including studies leading up to Phase I clinical trial safety studies and GLP animal model pivotal efficacy studies. This FOA, however, will **NOT** support Phase I clinical trials or GLP animal model pivotal efficacy studies.

The priority areas of product development interests from proof of principle to submission of IND/IDE include but are not limited to the following examples:

- Medical products and regimens that mitigate and/or treat radiation injury post-exposure (i.e., administration of first dose to start at least 24 hours after radiation exposure), with emphasis on broad activity (i.e., multi-syndrome, multi-tissue), ease of administration in an emergency scenario, safety, and long shelf-life;
- Radionuclide decorporation agents that facilitate elimination of a range of radionuclides from the body or blocking agents that prevent the absorption of radionuclides in the body;
- Minimally invasive biodosimetry devices useful for emergency triage that can rapidly and accurately distinguish individuals who need treatment from those who do not, and that can identify and measure internal and external exposure; and
- New medical product formulations that can be easily administered to civilian populations including special populations (e.g., infants, children, elderly, and the immunocompromised) in emergency situations.

The overall goal of this program is the rapid development of safe and effective radiological/nuclear medical countermeasures for clinical use under emergency situations.

Guidance for the approval of decorporation agents to treat internal radionuclide contamination has been provided by the FDA and is available at <http://www.fda.gov/cder/guidance/6983fnl.htm>.

Studies in animal models will be required to demonstrate efficacy of the medical countermeasure products. It is anticipated that in most cases licensure or approval of proposed medical countermeasures will occur in accordance with the FDA Animal Rule (see 21 CFR 314.600 Subpart I for drug products and 21 CFR 601.90 Subpart H for biologic products <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm>).